VII. 510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular §807.92, the following summary of information is provided:

A. Submitted by:

Laetitia Bernard
Manager of Regulatory Affairs
NuVasive™, Incorporated
10065 Old Grove Road
San Diego, California 92131
Telephone: (858) 271-7070
Telefacsimile: (858) 271-7101

B. Device Name

Trade Name: *Hemi-Arc™ Surgical Navigator*

Common or Usual Name: *Arthroscope, Stereotaxic Frame*

Classification Name: *Arthroscope, Stereotaxic Instrument*

C. Predicate Devices

The subject *Hemi-Arc™ Surgical Navigator* is substantially equivalent to the Surgical Guide Frame currently manufactured and distributed commercially in the U.S. by NuVasive™, Inc.

D. Device Description

The *Hemi-Arc™ Surgical Navigator* essentially serves as an instrument holder and guide which is intended to be aligned with the operative site using real time, or near real-time (i.e. success static images) image-intensified C-arm fluoroscopy. The *Hemi-Arc™* guide frame is adjustable in several planes of motion, and their fluoroscopic alignment with spinal anatomical features provides the path of entry of subsequent arthroscopic instrumentation to be precisely controlled, thereby avoiding damage to surrounding tissues such as nerves or dura.

E. Intended Use

The NuVasive™ Guided Spinal Arthroscopy System consists of a *Surgical Navigator* with adjustable cannula guides, and various percutaneous surgical cannulae and instrumentation. This System is intended to assist in gaining controlled percutaneous access to, and visualization of, the spinal nerves, foramina, vertebra, intervertebral disc, and surrounding tissues of the spine via uniportal or biportal posterior, lateral, or posterolateral approach, where anatomical restrictions safely permit. It is intended for use under real-time, or near real-time (i.e., successive static image) radiographic visualization via image-intensified C-arm fluoroscopy. The System is designed for use with NuVasive™ spinal arthroscopes and percutaneous surgical instrumentation, but may be used with other arthroscopes and instrumentation having compatible diameter and length, and which are indicated for use in the spine.

F. Comparison to Predicate Devices

The subject device has indications for use identical to those of its predicate, and employs the same principles of operation for alignment with the spinal operative site using real time, or near real-time (i.e. success static images) image-intensified C-arm fluoroscopy to provide access to subsequent arthroscopic instrumentation. Due to this equivalency, the device raises no new safety or effectiveness issues.

G. Summary of Design Control Activities

Design control activities employed to control the development of the modification to the *Surgical Guide Frame* included:

- a comprehensive Risk Analysis to identify potential risks and failures associated with operation of the device, any mitigations incorporated to reduce or eliminate those risks and failures, and an assessment of residual risk;
- a comprehensive program of verification and validation activities demonstrating that acceptance criteria were met, and that design output satisfied design input.

H. Summary of Clinical Tests

(Not applicable.)

I. Conclusions

The subject device is substantially equivalent to the currently marketed predicate device, and its development has been adequately and appropriately conducted and validated under a comprehensive design control program complying with Title 21 CFR, §820.30.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 0 2001

Ms. Laetitia Bernard
Manager of Regulatory Affairs
Nuvasive, Inc.
10065 Old Grove Road
San Diego, California 92131

Re: K013257
Trade/Device Name: Hemi-Arc™ Surgical Navigator
Regulation Number: 882.4560, 888.1100
Regulation Name: Stereotaxic instrument
Arthroscope and accessories
Regulatory Class: II
Product Code: HAW, HRX
Dated: September 28, 2001
Received: October 1, 2001

Dear Ms. Bernard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walk, MS

for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

D. Indications for Use Statement

510(k) Number (if known): K013257

Device Name: *Hemi-Arc™ Surgical Navigator*

Indications for Use:

The NuVasive™ Guided Spinal Arthroscopy System consists of a *Surgical Navigator* with adjustable cannula guides, and various percutaneous surgical cannulae and instrumentation. This System is intended to assist in gaining controlled percutaneous access to, and visualization of, the spinal nerves, foramina, vertebra, intervertebral disc, and surrounding tissues of the spine via uniportal or biportal posterior, lateral, or posterolateral approach, where anatomical restrictions safely permit. It is intended for use under real-time, or near real-time (i.e., successive static image) radiographic visualization via image-intensified C-arm fluoroscopy. The System is designed for use with NuVasive™ spinal arthroscopes and percutaneous surgical instrumentation, but may be used with other arthroscopes and instrumentation having compatible diameter and length, and which are indicated for use in the spine.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K013257